

Part 2 – Remarks

This Amendment and Response is responsive to the Office Action mailed March 6, 2006. In that office Action claims 1-62 and 84-108 were allowed. Claims 75-79 and 81-83 were objected to as depending upon a rejected claim, but were noted as allowable if amended into independent form including all of the preceding limitations. Claims of 63-69, 71 and 80 were rejected as anticipated under 35 USC 102(b) as anticipated by US patent 5,222,938 to Behl. Claim 70 was rejected as obvious under 35 USC 103(a) from Behl. Claims 72-73 were rejected as obvious under 35 USC 103(a) from Behl and WO 94/01177 to Hascoet. Claim 74 was rejected as obvious under 35 USC 103(a) from Behl, Hascoet and US patent 5,500,012 to Brucker.

Reconsideration of these objections and rejections is respectfully requested. Claims 1-108 remain pending.

Allowed Claims

Claims 1-62 and 84-108 remain in their original, unamended form. In accordance with 37 CFR 1.173, it is not believed necessary to list these claims in an amendment to a reissue application. Accordingly, these allowed claims have not been listed in Part 1 above.

Allowable Claims

Claim 75 has been amended into independent form by incorporating the subject matter from claim 63 therein. All the limitations of claim 63 have been incorporated into amended claim 75, and therefore amended claim 75 should be allowable in accordance with the Examiner's notation of allowable subject matter. Claims 76-79 depend on amended claim 75 and should be allowable as well.

Claim 81 has been amended into independent form by incorporating the subject matter from claims 63 and 80 therein. All of the limitations of claims 63 and 80 have been incorporated in amended claim 81, and therefore amended claim 81 should be allowable in accordance with the Examiner's notation of allowable subject matter. Claims 82 and 83 depend on amended claim 81 and should be allowable as well.

Prior Art Rejections

1. Reconsideration of the anticipation rejection of claims 63-69, 71 and 80, based on Behl, is respectfully requested.

The rejection asserts that the Behl reference discloses an antenna, an expandable reservoir and a channel. The rejection apparently asserts that the remaining claim language is “for intended use” and that the Behl catheter is fully capable of being used in the manner recited by this language. It is believed that the rejection is in error because the claim limitations are not described by the Behl reference, and because the language in the claim is proper definitional language recited in functional form, not intended use language.

The complete recitation in claim 63 with respect to the antenna is that its emitted electromagnetic radiation therapeutically heats the surrounding tissue. Nothing in Behl discloses an antenna which heats tissue with emitted radiation. Behl discloses only heating a thermally conductive liquid medium which has been injected into an organ. The heated liquid medium therapeutically treats the tissue by thermal conduction, not by emitted electromagnetic radiation. Behl’s thermal heating element is directly in contact with the liquid medium to transfer thermal energy from the heating element into the liquid medium. Behl discloses only thermal temperature build-up of the liquid medium, and indeed depends only on thermal temperature build-up of the liquid medium. See column 7, lines 8-27.

As the office action correctly notes, Behl’s heating element can be a microwave emitter. Specifically, Behl states that the “microwave emitter (is) capable of heating the fluid directly.” Column 7, lines 21-22. Behl contains no apparent disclosure, or suggestion, of the use of a microwave emitter that also radiates electromagnetic energy through the liquid into the surrounding tissue to create a separate radiation-induced therapeutic region, apart from and in addition to the therapeutic region created by the thermal heat contained in the liquid. Claim 63, in its more specific language, requires the antenna to emit electromagnetic radiation into the tissue to create a therapeutic region from that emitted electromagnetic radiation. This feature is not disclosed in Behl.

The complete recitation in claim 63 with respect to the expandable reservoir is that it has an extent of radial expansion which is sufficient to compress tissue against the reservoir and reduce blood flow through the compressed tissue to reduce the removal of heat by blood flow away from the compressed tissue. No such comparable disclosure is apparent in Behl. Once Behl injects the liquid into the organ, presumably that liquid attains the same pressure as the organ itself. Therefore, there would appear to be no compression that would reduce the blood flow. As is correctly noted in the Office Action, Behl does disclose inflating a balloon, but that inflation is for the purpose of "occluding a duct or passage which would otherwise allow drainage of the thermally conductive medium from the hollow body organ during the course of treatment." Column 8, lines 5-8. In other words, it appears as though Behl's balloon is to create a barrier to confine the heated liquid in hollow organs.

Nothing in Behl appears to disclose or suggest the greater effectiveness of a therapeutic heat treatment created by restricting the blood flow so that the blood does not carry the therapeutic thermal energy away from the tissue which is treated. A balloon with a capability of expanding enough to create a barrier, and a balloon with a capability of expanding enough to compress the tissue to restrict blood flow, as recited in claim 63, are entirely different things, because creating a barrier is likely to be achieved by use of considerably less compression than that necessary to restrict the blood flow. In any event, there is no disclosure in Behl of compressing the tissue to restrict the blood flow. Indeed, if Behl was to compress the tissue to restrict blood flow it seems likely that that level of compression would also restrict the permeation of the thermally conductive fluid medium into the organ as is specifically required by Behl. Restricting blood flow was not disclosed by Behl.

The complete recitation in claim 63 with respect to the expandable reservoir is that it has a capacity for transmitting sufficient electromagnetic radiation emitted from the antenna to heat therapeutically the second region of tissue beyond the first region which is heated by thermal conduction. As is discussed above in conjunction with the antenna, Behl's the microwave emitter heats the liquid only within the reservoir. Accordingly, there is no disclosure or suggestion in Behl that the antenna and the expandable reservoir

permit the emitted microwave radiation to transfer through the reservoir and penetrate into the tissue to create the electromagnetic radiation-induced second therapeutic region beyond the thermal energy-induced the first therapeutic region. They will does not disclose electromagnetic radiation and thermal energy treatment regions.

As to the allegation of intended use recited with in claim 63, the relationships recited in the claim are structural and are defined in relation the physiology in which the catheter is intended to be used. This is not to say, however, that those relationships are not proper claim limitations because they depend on physiology for definition. An invention can be defined by what it is as well as what it does. The Examiner may wish to consider the case of In re Gulack, 706 F.2d 1381, 217 USPQ 401 (CAFC 1983), in this regard. The holding of the case states that it is improper to dissect a claim, excise portions from that claim and then declare the remaining portion of the mutilated claim to be unpatentable. The case makes it clear that the only time it is appropriate to give no patentable weight to any nonstatutory subject matter is when that nonstatutory subject matter is not structurally or functionally related with the other limitations of the claim. Here all of the limitations are structurally or functionally related, and should be entitled to consideration.

Full consideration of the entire limitations of claim 63 reveal that it is not disclosed and therefore not anticipated by Behl. Withdrawal of the anticipation rejection is respectfully requested.

Claims 64-69, 71 and 80, depend directly or indirectly on claim 63. Accordingly, the subject matter of these claims is not anticipated for the same reasons that claim 63 is not anticipated by Behl. Claim 64 relates to the distinction between the first and second therapeutically treated regions; Behl does not discuss two treatment regions. Claim 65 relates to a capacity of the reservoir to treat a bladder neck and expand a urine passageway therethrough; Behl does not disclose an expandable reservoir which has this capability. Claim 66 discusses a feed cable and a cooling channel for conducting fluid to remove heat from the feed cable. Although Behl does not disclose a feed cable, such a device must inherently be present to feed electrical energy to the microwave emitter. However, Behl does not teach or suggest the use of a cooling channel for the microwave

feed cable. Indeed, because the microwave emitter in Behl is intended only to heat the liquid, it may be that a cooling channel for the microwave feed cable is not required. Because there is no cooling channel disclosed in Behl, there is no disclosure of the cooling channel being separate from a channel communicating with Behl's balloon, as recited in claim 67. For the same reasons of Behl failing to disclose a cooling channel, there is no disclosure in Behl of his balloon being separated from the cooling channel as in claim 68. Nor does Behl discuss preventing fluid circulation within the reservoir as in claim 69. The claims are also distinguished from Behl by other limitations.

2. Reconsideration of the obviousness rejection of claim 70 in view of Behl is respectfully requested.

As noted with respect to the first rejection, the rejected claims relate to the creation of two therapeutic regions. The type of heat therapy (microwave and conductive) is entirely different, and each has its own particular characteristics. It would not be simply a matter of adding additional temperature sensors, as alleged in the Office Action, because the two different types of therapeutic effects created have their own constraints and needs for temperature sensors. As noted above, Behl does not suggest two different therapeutic regions. Consequently, the obviousness rejection based on Behl does not fairly address the limitations of claim 70.

3. Reconsideration of the obviousness rejection of claims 72 and 73 in view of Behl and Hascoet is respectfully requested.

As noted above with respect to the first and second rejections, Behl fails to disclose or suggest the creation of two therapeutically treated regions, with the therapeutic treatment in each region resulting from a different type of energy application. As noted above with respect to the second rejection, there are reasons to have temperature sensors in each of the zones. Behl has no capability of, or need for, a temperature sensor in a zone remote from that zone where the thermally conductive liquid medium has been heated. Hascoet does not appear to be concerned with two therapeutically treated regions, one of which results from a liquid medium which has been heated thermally. Accordingly, there is no suggestion in either Behl or Hascoet to suggest combining their subject matter. The present application is the only suggestion for

such a relationship between these references. Of course the use of the present application as a basis for combining references is an impermissible use of hindsight. Accordingly, is respectfully suggested that the obviousness rejection of claims 72 and 73 is erroneous, and should be withdrawn.

4. Reconsideration of the obviousness rejection of claim 74 in view of the combination of Behl, Hascoet and Brucker is respectfully requested.

Claim 74 involves the creation of two therapeutically treated regions, and those regions are created by different therapies, i.e. emitted electromagnetic radiation and thermal conduction. The regions are located differently relative to the catheter. Like Behl and Hascoet, Brucker is not apparently concerned with creating two regions by using different therapies. Brucker discloses the application of laser or RF energy to tissue. The temperature sensors used by Brucker are intended to measure the effects of a single type of energy application. Nothing in Brucker, or Behl or Hascoet, suggests the concept of the electromagnetic emission and thermal conductivity used simultaneously to create different therapeutically treated zones, so accordingly there is believed to be no appropriate basis to combine these references in a valid obviousness rejection. Reconsideration and withdrawal of the obviousness rejection is respectfully requested.

Conclusion

As a result of the amendments and remarks set forth above, it is believed that all pending claims in this application are in condition for allowance. Allowance is respectfully requested. The Examiner is requested to contact the undersigned by telephone to discuss any issues which may inhibit the immediate allowance of the claims.

It is noted that the original US patent 6,366,818 has not yet been surrendered, although an offer to do so has been made of record.

Respectfully submitted,

Date: June 6, 2006

By: 

John R. Ley
Registration No. 27,453
ATTORNEY FOR APPLICANT
JOHN R. LEY, LLC
5299 DTC Boulevard, Suite 610
Greenwood Village, CO 80111-3321
Telephone: (303) 740-9000